



**The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Department of Public Health  
Bureau of Health Care Safety and Quality  
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**TO: Interested Parties  
Health Care Organizations and Professional Associations**

**From: John Auerbach, Commissioner, Department of Public Health  
Jean Pontikas, Interim Director, Bureau of Health Care Safety and Quality**

**Date: September 4, 2009**

**Re: EMERGENCY REGULATIONS AUTHORIZING ADMINISTRATION OF VACCINE  
BY DESIGNATED HEALTH CARE PROFESSIONALS**

Introduction

This memorandum is to inform you that the Department of Public Health plans to propose to the Public Health Council on September 9, 2009 emergency regulations authorizing the Commissioner of Public Health to designate certain health care professionals to administer seasonal influenza and H1N1 vaccine. The amendments are part of the Department's planning and preparation for pandemic influenza A H1N1 2009 this fall. If approved by the Council, the amendments would go into effect on September 14, 2009, upon filing with the Office of the Secretary of the Commonwealth.

An overview of the proposed amendments, regulatory process, protocols, training requirements, potential impact on individuals in the impacted professions and information on vaccination and vaccine availability is provided below and in the accompanying and referenced materials.

Proposed Emergency Regulations

In brief, the proposed emergency amendments would authorize the Commissioner to issue an order designating health care professionals, licensed or certified by the Department, or medical or nursing students enrolled in approved or accredited programs, to administer vaccine for the prevention of pandemic, novel or seasonal influenza virus. Such an order would be issued in the event the Commissioner determines that there are or will be

insufficient health care professionals available for timely vaccine administration. An advance copy of the proposed regulatory amendments, at 105 CMR 700.000, is attached as Attachment A.

### Commissioner's Order

The Commissioner's Order would identify those additional groups that may administer vaccine and the conditions under which such authorization would be applicable. In addition, the Order would reference and be accompanied by guidance on the training required, protocols for vaccination and recordkeeping as well as other requirements. In addition, the regulations would require that the vaccine be administered under an order or prescription of a practitioner authorized to prescribe vaccines.

The Commissioner expects to issue an order, along with associated guidelines and protocols, on or after September 14, 2009 when the regulatory amendments would go into effect. When issued, the Commissioner's Order is expected to designate dentists, paramedics and pharmacists as authorized vaccinators. An advance copy of the draft guidelines concerning training and supervision of vaccine administration, which would accompany the Order, is attached as Attachment B). The written protocols concerning storage, handling and other parameters of vaccine management, which would be referenced in the Order, are addressed below and in the draft guidelines.

The Commissioner's Order and associated guidelines and written protocols may change throughout the flu season dependent upon emerging conditions and as needed. At the September 9 Public Health Council meeting the Council will consider adding medical and nursing students as potential vaccinators in a revised version of the emergency regulation. If passed, the Commissioner may (but need not necessarily) issue an order and guidelines at a later date authorizing such students and/or other licensed or certified health care professionals as vaccinators.

### Implementation Issues

With respect to questions concerning liability, the federal Public Readiness and Emergency Preparedness Act of 2006 (PREP Act; 42 U.S.C. § 247d–6d) provides immunity from tort liability under state and federal law for health care professionals designated as H1N1 vaccinators by the regulations and Commissioner's Order. It should be noted that PREP Act immunity does not extend to seasonal flu vaccination. The liability issues surrounding administration of seasonal flu will be no different than in prior flu seasons.

In terms of reimbursement, while the H1N1 vaccine will be provided at no charge, reimbursement for vaccine administration is a matter between providers and third party payers. Seasonal flu vaccine will be available as in previous flu seasons. Reimbursement for seasonal vaccine and administration is similarly a matter for providers and third party payers.

Once the Commissioner's Order is issued, those organizing community or facility-based flu clinics may determine whether to engage newly authorized vaccinators in administering seasonal and H1N1 vaccine.

## Regulatory Process

While the Public Health Council passed an emergency regulation regarding potential vaccinators at its August 12, 2009 meeting, that regulation has not been formally filed yet. As noted above, a revised emergency regulation will be considered by the Public Health Council at its regularly scheduled meeting on September 9, 2009 and, pending approval by the Council, will go into effect on September 14, 2009, upon filing with the Office of the Secretary of the Commonwealth.

The August emergency regulation is explained in detail in the Public Health Council memorandum of August 12, 2009 available on the DPH website [www.mass.gov/dph](http://www.mass.gov/dph). The amendments to be considered on September 9, 2009 will propose adding medical and nursing students as potential vaccinators as well as adding administration of seasonal influenza vaccine by authorized vaccinators.

A public hearing and comment period will be held concerning the emergency regulations. Please consult the DPH website for an announcement of the hearing, to be made on or after September 14, 2009.

## Availability of H1N1 Vaccine

The H1N1 vaccine is now in production, with efficacy and safety studies ongoing. Initial quantities of H1N1 influenza vaccine will be available starting in October. All H1N1 vaccine will be supplied by the federal government at no cost to providers in both the public and private sectors. State health departments will be responsible for allocating all doses of H1N1 vaccine.

The first shipments of H1N1 vaccine are likely to be directed to priority populations such as children, pregnant women, those of all ages at higher risk of complications of influenza infection, as well as healthcare workers and emergency medical services personnel with direct patient contact. It is expected that most people will require two doses of vaccine, 3-4 weeks apart. In addition, it is expected that H1N1 vaccine will be able to be co-administered with seasonal flu vaccine. The Department will post the latest guidance about priority groups and all other recommendations related to H1N1 vaccine on the Department's flu website <http://www.mass.gov/dph/flu>.

In order to facilitate allocation of H1N1 vaccine to providers in Massachusetts, the Department is developing an on-line system to register all public and private provider sites interested in receiving and administering novel H1N1 vaccine (including private providers, hospitals, local health departments, regional public health coalitions, visiting nurses associations, clinics, pharmacies and commercial community vaccinators). The Department expects to go live with this registration system in early September. Information about accessing the registration site will be disseminated broadly through email and in collaboration with professional organizations and trade associations, and will be posted on the Department's flu website <http://www.mass.gov/dph/flu>.

The task of administering millions of doses of seasonal and pandemic influenza vaccine is enormous. The Department will work closely with health care facilities, agencies, local health officials, and health care professionals to promote and support enhanced seasonal flu clinics.

#### Written Protocols

The Department's written clinic protocols covering the latest guidance and requirements about vaccine ordering, storage, provision of information and documentation can be found at <http://www.mass.gov/dph/imm>, and then click on "Vaccine Management." Standing orders for vaccines and clinic protocols can be found by going to <http://www.mass.gov/dph/imm> and clicking on "Model Standing Orders." Additional guidance and other resources for immunization training can also be found on the DPH website.

#### Latest Information on Influenza Outbreak and Vaccination

There is helpful information about flu vaccine, including the risks and benefits of getting vaccinated, and H1N1 guidance, on the Centers for Disease Control and Prevention's (CDC's) website at <http://www.cdc.gov/flu>. For the latest updates on influenza also please visit the Department's website at [www.mass.gov/dph/flu](http://www.mass.gov/dph/flu).

#### Contact Information

If you have any questions concerning the proposed emergency amendments, please contact the Drug Control Program at 617-983-6700 or [dcp.dph@state.ma.us](mailto:dcp.dph@state.ma.us). Questions concerning vaccine administration, training and management should be directed to the Immunization Program at 617-983-6800.